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- 10. The formulation of claim 1, wherein the formulation comprises 400 mcg of fentanyl, a free base or a pharmaceutically acceptable salt thereof, or a derivative thereof, and provides one or more mean pharmacokinetic values selected from the group consisting of: AUC_{last} 4.863+/-1.70821 hr*ng/mL, AUC_{inf} 5.761+/-1.916 hr*ng/mL, and AUC_{extrap} 10.26+/-5.66%, when administered to humans.
- 11. The formulation of claim 1, when administered to humans, which provides a dosage amount of fentanyl, a free base or a pharmaceutically acceptable salt thereof, or a derivative thereof which is substantially dose proportional to the dosage which contains about 400 mcg fentanyl selected from the group consisting of about 100 mcg, about 200 mcg, about 600 mcg, about 800 mcg, and provides one or more pharmacokinetic values selected from the group consisting of mean AUC_{last} , mean AUC_{inf} , and mean AUC_{extrap} .
- 12. The formulation of claim 1, which provides a substantially dose proportional mean AUC_{last} based on a mean AUC_{last} of about 4.863+/-1.70821 hr*ng/mL for a 400 mcg 20 fentanyl dose when administered to humans.
- 13. The formulation of claim 1, wherein the formulation comprises a 400 mcg dose of fentanyl, a free base or a pharmaceutically acceptable salt thereof, or a derivative thereof, providing a geometric mean $\ln(C_{max})$ of about 25 0.7865 ng/ml when a dose is administered to humans.
- 14. The formulation of claim 1, wherein the formulation comprises a 400 mcg dose of fentanyl, a free base or a pharmaceutically acceptable salt thereof, or a derivative thereof, providing a mean $F(AUC_{last})$ of about 0.721+/-0.199 ng/mL when a dose is administered to humans.
- 15. The formulation of claim 1, wherein the formulation comprises a 400 mcg dose of ffentanyl, a free base or a pharmaceutically acceptable salt thereof, or a derivative thereof when a dose is administered to humans, providing a mean F (bioavailability) selected from the group consisting

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- of: about 71%+/-16%, 0.721+/-0.199 based on ${\rm AUC}_{last}$ and about 0.756+/-0.212 based on ${\rm AUC}_{inf}$ or combinations thereof.
- **16.** The formulation of claim **1**, wherein the formulation further comprises water.
- 17. The formulation of claim 1, wherein the formulation provides a substantially dose proportional mean C_{max} based on a mean C_{max} of about 0.813 ng/ml+/-0.252 for a 400 mcg fentanyl dose when administered to humans.
- **18**. The formulation of claim **1**, wherein the formulation provides a substantially dose proportional mean AUC_{last} based on a mean AUC_{last} of about 4.863+/-1.70821 hr*ng/mL for a 400 mcg fentanyl dose when administered to humans.
- 19. The formulation of claim 1 wherein the formulation provides a mean time to the lower limit of quantification (LLOQ) of fentanyl of about 5 minutes.
- **20**. The formulation of claim **1** wherein the formulation provides a mean time to maximum plasma concentration (T_{max}) after administration to humans of from about 5 to about 120 minutes.
- 21. A sublingual spray formulation for the treatment of pain comprising:
 - (i) from about 0.1% to about 0.8% by weight of fentanyl, a free base or a pharmaceutically acceptable salt thereof;
 - (ii) from about 50% to about 60% by weight of ethanol; and
 - (iii) from about 4% to about 6% by weight of propylene glycol,

wherein the formulation provides a mean time to 60% maximum plasma concentration (T_{max}) of fentanyl of about 10 minutes, is propellant-free and comprises droplets having a mean diameter of at least about 10 microns and wherein the formulation provides a mean time to the lower limit of quantification (LLOQ) of fentanyl of about 5 minutes.

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